UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OCT 22 1999

MEMORANDUM

SUBJECT: Need for Updated Reference Dose for Perchlorate

FROM: Timothy Fields, Jr.
Assistant Administrator
Office of Solid Waste and Emergency Response

J. Charles Fox
Assistant Administrator
Office of Water

TO: Norine Noonan, Ph.D.
Assistant Administrator
Office of Research and Development

The purpose of this memorandum is to request a meeting with you and your staff at your earliest convenience to discuss the need of OSWER and OW for an updated reference dose for the perchlorate ion by the Spring of 2000. There are a number of hazardous waste sites with perchlorate contamination at which timely clean-up decisions are needed. In addition, OW has the near term priority of developing a drinking water health advisory for perchlorate to provide guidance to States and communities where drinking water supplies have become contaminated. A longer term priority also exists for OW to make a regulatory determination on perchlorate. We are therefore requesting ORD assistance in developing this value in accordance with an expedited schedule.

BACKGROUND

In February, 1999, the draft toxicity review document on perchlorate prepared by the ORD National Center for Environmental Assessment (NCEA) based to a large extent upon toxicology studies initiated in 1997 and thereafter, underwent independent peer review at a public workshop in San Bernardino, CA. It has been known for a number of years that perchlorate is a thyroid toxicant. The peer review panel recommended that the thyroid tissue slides from several of the studies be evaluated by a "pathology working group" (PWG). It also concluded that based upon the available toxicity data base, the reference dose (RfD) proposed in the document (0.0009 mg/kg/day) "is likely to be conservative." Some reviewers also made recommendations for additional toxicology studies, including the performance of studies that would be useful in physiologically-based pharmacokinetic (PB-PK) modeling.

NCEA arranged for the National Toxicology Program (NTP) to perform a PWG review of the thyroid slides from a number of the recent studies. The time frame originally projected for this review was August 1999. ORD staff, however, were not able to meet this time frame, and the meeting was scheduled for November 9, 1999, in Research Triangle Park, N.C. We just learned from NTP staff on October 14 that the meeting was again delayed, this time until January 19 - 21, because ORD has not yet completed its review. This is five months beyond the originally projected time frame. EPA programs and a number of States have been waiting for these key data.

With respect to the studies that will contribute to PB-PK modeling, we understand from ORD/NCEA that the Air Force still plans to perform all or most of them, even though funding approval for some of the studies has been delayed.

On September 10, staff from OSWER and EPA Region 9, and Dr. William Farland, ORD, met with representatives of Lockheed Martin and Aerojet General Corporation, who requested that OSWER write to the State of California, requesting that California postpone developing a Public Health Goal (PHG) for perchlorate until the completion of the pending toxicity/pharmacokinetics studies and the finalization of the ORD/NCEA toxicity review document on perchlorate following a second peer review. At that point in time, California was planning to issue such a standard by the end of 1999; we understand that California has since decided to wait until after the completion of the NTP PWG review to issue its toxicity standard. (This decision, however, was dependent in part upon the November 1999 time frame for the NTP PWG.) At the September 10 meeting, Dr. Farland estimated that the final ORD toxicity review document should be available in early calendar year 2001.

REASONS FOR REQUEST

OSWER and OW need an updated reference dose for perchlorate by the Spring of 2000 for a number of reasons. First, perchlorate contamination of ground water and/or surface waters exists at a number of sites. Clean-up decisions at certain hazardous waste sites have been delayed several times. Most recently they were delayed after the February 1999 peer review on the basis that ORD would finalize a new reference dose for perchlorate this Fall. Such decisions need to be made without further delays. Likewise, OW has delayed developing a drinking water health advisory on perchlorate. OW needs to take action in a timely manner.

In addition, significantly more data now exist on the toxicology of perchlorate than do for numerous environmental contaminants that the Agency has regulated. We believe that an updated and reliable reference dose can be developed upon receipt of the report of the NTP PWG review of the thyroid slides. If the PB-PK model that ORD develops upon completion of the planned Air Force studies indicates that the ultimate reference dose should be different than the updated value, the needed change can be made at that time. This is consistent with the ongoing policy of the Agency with respect to the evaluation of the hazards of environmental pollutants.

ORD CONTRIBUTIONS TO UNDERSTANDING PERCHLORATE TOXICITY

ORD is to be commended on its contributions to the understanding of the toxicology of the perchlorate ion, on its stimulation of needed research by the Air Force and the private sector, on its evaluation of the data generated thus far, and on its preparation of the December 1998 draft toxicity review document. It would be unfortunate if the State of California (or the Agency for Toxic Substances and Disease Registry, which is also working on a draft toxicological profile on perchlorate) were to promulgate their own toxicity values prior to the Agency, given the critical role of ORD in the generation of the necessary data base.

NEED FOR ACTION

We hope that you will be able to meet with us on this important issue without delay, since time is of the essence. It is critical that the NTP PWG take place no later than January 19 -21, 2000, so that a new reference dose for perchlorate can be developed by the Spring of 2000. The commitment of the needed ORD resources and staff time is key to ensuring that there are no further delays.

If ORD concludes that it is appropriate to produce a PB-PK model prior to updating its toxicity review document and issuing a revised reference dose for perchlorate, we will certainly respect that decision. But we will have to find another mechanism for generating in a timely manner a revised reference dose for use in our programs.

We will call you about arranging a meeting to pursue these two issues.

cc: M. Shapiro
D. Canter
P. Grevatt
L. Hofmann
J. Wiltse
C. Dougherty
M. Osinski
W. Farland
A. Jarabek
K. Takata